

## REMARKS

This submission is responsive to the Office Action dated June 17, 2009. Applicant has not amended the claims. Claims 1, 5-19, 23-38, and 42-56 remain pending.

### **Claim Rejection Under 35 U.S.C. § 112**

In the Office Action, the Examiner rejected claims 1, 5-19, 23-38 and 42-56 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner alleged that the claim 1 feature “monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event” (emphasis added) and similar features in independent claims 19, 38, and 56 are not described by Applicant’s disclosure in such a way as to convey to one skilled in the art that Applicant possessed the claimed invention at the time of filing. Applicant respectfully disagrees, and traverses this rejection.

The Examiner acknowledged that Applicant’s disclosure describes defining an event based on monitoring the sensor output during the event and/or a learning mode, and monitoring therapy during the event and/or during the learning mode. However, the Examiner alleged that no support was found in Applicant’s disclosure for monitoring therapy while defining the event (i.e., monitoring the output of the sensor). The Examiner asserted that just because the monitoring of therapy and the monitoring of the sensor output occur during a common period, such as a learning mode, does not mean that one occurs while the other occurs because both could occur in the period but at different times. The Examiner concluded that monitoring therapy while the output of the sensor is monitored appears to be an unsupported range of when the monitoring the therapy and monitoring the sensor acts occur.

The Examiner cited the depicted order of functions 82 and 84 in FIG. 6 as providing support for monitoring the therapy occurring subsequent to monitoring the sensor output. Applicant agrees that the application provides support for monitoring the therapy occurring subsequent to monitoring the sensor output. However, neither the depicted order of functions 82 and 84 in FIG. 6, nor any other portion of the application precludes any overlap of monitoring the therapy and monitoring the sensor output. On the contrary, considering the application as a whole, one of ordinary skill in the art would have understood Applicant to possess embodiments

in which monitoring the therapy at least partially overlaps with monitoring of the sensor output to define the event.

One of ordinary skill in the art would have recognized that Applicant possessed the claimed invention based at least on the non-limiting example of paragraph [0035]. Paragraph [0035] states “[p]atient 14 may...simply begin running and allow IMD 12 to record an exemplar of the sensor output while patient 14 is running.... [W]hile patient 14 is running...patient 14 uses programming device 20, e.g., keypad 24, to change one or more stimulation parameters in an attempt to maintain adequate symptom control during the activity (emphasis added).” Furthermore, paragraph [0059] states “patient 14 adjusts stimulation parameters over a period of time after directing IMD 12 to enter the learning mode, e.g., during the event...so that IMD 12 learns appropriate adjustments to therapy to provide while patient 14 is running, and may adjust stimulation parameters while running to maintain effective and comfortable neurostimulation therapy.” (Emphasis added).

Paragraph [0062], which describes FIG. 6, states that “[p]rocessor 34 may record the sensor output or information over any length of time, may record multiple samples, and may make the recording or recordings at any time after entering the learning mode. Processor 34 may store the recording(s), or the result of an analysis, e.g. feature, Fourier, or wavelet, or the recording(s) in memory 36 as an event 52. Processor 34 records therapy information as a learned therapy 54 during operation in the learning mode (84), and associates the learned therapy 54 with the defined event 52 (86), as described above with reference to FIG. 5.” (Emphasis added). Paragraph [0066] goes on to state “[f]or example, an event 52 may be patient 14 running, and the learned therapy 54 may include changes to stimulation parameters occurring at associated times during the “running” event such that effective and comfortable therapy is maintained.” (Emphasis added).

It is clear from the cited paragraphs that an event may comprise sensor output, e.g., a plurality of values of a signal, recorded during a period of time during an activity, such as running. It is also clear that the monitoring of the therapy may occur during the activity and, more particularly, during the event, so that an IMD or other device learns appropriate adjustments to therapy to provide during the event (when subsequently detected) to maintain effective and comfortable neurostimulation therapy.

One of ordinary skill in the art would not have read Applicant's disclosure in a manner such that the act of monitoring therapy and the act of monitoring the sensor output could not occur at the same or overlapping times. Such a reading would be consistent with the advantages that may be achieved according to the application. Applicant's paragraph [0011] describes that a possible advantage is to provide a medical device that can "provide therapy that better addresses changes in the symptoms of a patient and/or level of efficacy or side effects of the therapy associated with an activity undertaken by the patient (emphasis added)." One of ordinary skill in the art would understand that monitoring for therapy changes during the definition of the event, rather than after the event had been defined and may have ended, would have facilitated addressing changes in symptoms during a subsequent occurrence the event.

The Examiner recognized that the requirement of the written description is whether the specification reasonably conveyed to one of ordinary skill in the art that Applicant had possession of the claimed invention at the time of filing. To show that the Applicant did not have possession of the claimed invention, the Examiner suggested that the act of monitoring therapy and the act of monitoring the sensor output could happen at different times. However, the Examiner failed to provide any reason why one of ordinary skill in the art would read Applicant's disclosure such that the act of monitoring therapy and the act of monitoring the sensor output would only happen at different times. In fact, for all the reasons described above, one of ordinary skill in the art would have read Applicant's disclosure in such a manner that the act of monitoring therapy and the act of monitoring the sensor output would have occurred at the same time.

For at least all the reasons advanced above, Applicant's disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing. Applicant respectfully requests withdrawal of the 35 U.S.C. § 112, first paragraph rejection for claims 1, 19, 38, and 56. The Examiner rejected the various dependent claims under 35 U.S.C. § 112, first paragraph due to their dependency upon claims 1, 19, and 38. Since the 35 U.S.C. § 112, first paragraph rejection is improper for claims 1, 19, and 38, the 35 U.S.C. § 112, first paragraph rejection for the various dependent claims is improper. Applicant respectfully requests withdrawal of the 35 U.S.C. § 112, first paragraph rejection for the various dependent claims.

Furthermore, Applicant draws the Examiner's attention to the requirements of MPEP 2163(III). MPEP 2163(III) requires the Examiner to evaluate the patentability of the claims on all statutory grounds even when rejecting the claims under 35 U.S.C. §112, first paragraph. Since the Examiner failed to reject the claims on any statutory grounds other than 35 U.S.C. §112, first paragraph, the Examiner seemed to recognize that the claims recite novel and non-obvious patentable subject matter. Accordingly, Applicant submits that the claims are in condition for immediate allowance and respectfully requests the Examiner to indicate as such.

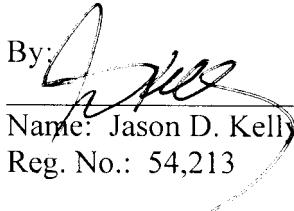
### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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9-19-09

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